

108TH CONGRESS  
1ST SESSION

# H. R. 616

To amend the Internal Revenue Code of 1986 with respect to the purchase of prescription drugs by individuals who have attained retirement age, and to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs and the sale of such drugs through Internet sites.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2003

Mr. PAUL introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend the Internal Revenue Code of 1986 with respect to the purchase of prescription drugs by individuals who have attained retirement age, and to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs and the sale of such drugs through Internet sites.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*



1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Prescription Drug Af-  
3 fordability Act”.

4 **TITLE I—AMENDMENTS TO IN-**  
5 **TERNAL REVENUE CODE OF**  
6 **1986**

7 **SEC. 101. INCOME TAX CREDIT FOR PRESCRIPTION DRUGS**  
8 **PURCHASED BY INDIVIDUALS WHO HAVE AT-**  
9 **TAINED RETIREMENT AGE.**

10 (a) IN GENERAL.—Subpart A of part IV of sub-  
11 chapter A of chapter 1 of the Internal Revenue Code of  
12 1986 (relating to nonrefundable personal credits) is  
13 amended by inserting after section 25B the following new  
14 section:

15 **“SEC. 25C. PRESCRIPTION DRUGS PURCHASED BY INDIVID-**  
16 **UALS WHO HAVE ATTAINED SOCIAL SECU-**  
17 **RITY RETIREMENT AGE.**

18 “(a) IN GENERAL.—In the case of an individual who  
19 has attained social security retirement age, there shall be  
20 allowed as a credit against the tax imposed by this chapter  
21 for the taxable year an amount equal to 80 percent of the  
22 amount paid by the taxpayer during the taxable year (and  
23 not compensated for by insurance or otherwise) for any  
24 prescribed drug (as defined in section 213(d)(3)) for use  
25 by such individual.



1       “(b) SOCIAL SECURITY RETIREMENT AGE.—For  
 2 purposes of this section, the term ‘social security retire-  
 3 ment age’ means retirement age (as defined in section  
 4 216(l)(1) of the Social Security Act).

5       “(c) DENIAL OF DOUBLE BENEFIT.—

6               “(1) COORDINATION WITH MEDICAL EXPENSE  
 7 DEDUCTION.—The amount which would (but for this  
 8 subsection) be taken into account by the taxpayer  
 9 under section 213 for the taxable year shall be re-  
 10 duced by the credit (if any) allowed by this section  
 11 to the taxpayer for such year.

12              “(2) COORDINATION WITH MEDICAL SAVINGS  
 13 ACCOUNTS.—No credit shall be allowed under this  
 14 section for amounts paid from any medical savings  
 15 account (as defined in section 220(d)).

16       “(d) ELECTION NOT TO HAVE CREDIT APPLY.—  
 17 This section shall not apply to a taxpayer for a taxable  
 18 year if the taxpayer elects not to have this section apply  
 19 for such year.”

20       (b) CLERICAL AMENDMENT.—The table of sections  
 21 for subpart A of part IV of subchapter A of chapter 1  
 22 of such Code is amended by inserting after the item relat-  
 23 ing to section 25B the following new item:

“Sec. 25C. Prescription drugs purchased by individuals who have  
 attained social security retirement age.”



1 (c) EFFECTIVE DATE.—The amendments made by  
 2 this section shall apply to taxable years beginning more  
 3 than 1 year after the date of the enactment of this Act.

4 **TITLE II—AMENDMENTS TO FED-**  
 5 **ERAL FOOD, DRUG, AND COS-**  
 6 **METIC ACT**

7 **SEC. 201. FACILITATION OF IMPORTATION OF DRUGS AP-**  
 8 **PROVED BY FOOD AND DRUG ADMINISTRA-**  
 9 **TION.**

10 (a) IN GENERAL.—Chapter VIII of the Federal  
 11 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)  
 12 is amended—

13 (1) by striking section 804; and

14 (2) in section 801(d)—

15 (A) by striking paragraph (2); and

16 (B) by striking “(d)(1)” and all that fol-  
 17 lows through the end of paragraph (1) and in-  
 18 serting the following:

19 “(d)(1)(A) A person who meets applicable legal re-  
 20 quirements to be an importer of drugs described in sub-  
 21 paragraph (B) may import such a drug (without regard  
 22 to whether the person is a manufacturer of the drug) if  
 23 the person submits to the Secretary an application to im-  
 24 port the drug and the Secretary approves the application.



1 “(B) For purposes of subparagraph (A), the drugs  
2 described in this subparagraph are drugs that are subject  
3 to section 503(b)(1) or that are composed wholly or partly  
4 of insulin.

5 “(C) The Secretary shall approve an application  
6 under subparagraph (A) if the application demonstrates  
7 that the drug to be imported meets all requirements under  
8 this Act for the admission of the drug into the United  
9 States, including demonstrating that—

10 “(i) an application for the drug has been ap-  
11 proved under section 505, or as applicable, under  
12 section 351 of the Public Health Service Act; and

13 “(ii) the drug is not adulterated or misbranded.

14 “(D) Not later than 60 days after the date on which  
15 an application under subparagraph (A) is submitted to the  
16 Secretary, the Secretary shall—

17 “(i) approve the application; or

18 “(ii) refuse to approve the application and pro-  
19 vide to the person who submitted the application the  
20 reason for such refusal.

21 “(E) This paragraph may not be construed as affect-  
22 ing any right secured by patent.”.

23 (b) CONFORMING AMENDMENTS.—Section 801(d) of  
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
25 381(d)) is amended—



1 (1) by redesignating paragraphs (3) and (4) as  
2 paragraphs (2) and (3), respectively; and

3 (2) in paragraph (3) (as so redesignated) by  
4 striking “paragraph (3)” each place such term ap-  
5 pears and inserting “paragraph (2)”.

6 **SEC. 202. INTERNET SALES OF PRESCRIPTION DRUGS.**

7 Section 503(b) of the Federal Food, Drug, and Cos-  
8 metic Act (21 U.S.C. 353(b)) is amended by adding at  
9 the end the following paragraph:

10 “(6)(A) With respect to the interstate sale of a pre-  
11 scription drug through an Internet site, the Secretary may  
12 not with respect to such sale take any action under this  
13 Act against any of the persons involved if—

14 “(i) the sale was made in compliance with this  
15 Act and with State laws that are applicable to the  
16 sale of the drug; and

17 “(ii) accurate information regarding compliance  
18 with this Act and such State laws is posted on the  
19 Internet site.

20 “(B) For purposes of subparagraph (A), the sale of  
21 a prescription drug by a person shall be considered to be  
22 an interstate sale of the drug through an Internet site if—

23 “(i) the purchaser of the drug submits the pur-  
24 chase order for the drug, or conducts any other part



1 of the sales transaction for the drug, through an  
 2 Internet site; and

3 “(ii) pursuant to such sale, the person intro-  
 4 duces the drug into interstate commerce or delivers  
 5 the drug for introduction into such commerce.

6 “(C) Subparagraph (A) may not be construed as au-  
 7 thorizing the Secretary to enforce any violation of State  
 8 law.

9 “(D) For purposes of this paragraph, the term ‘pre-  
 10 scription drug’ means a drug that is subject to paragraph  
 11 (1).”.

12 **SEC. 203. REGULATIONS OF SECRETARY OF HEALTH AND**  
 13 **HUMAN SERVICES; EFFECTIVE DATE.**

14 (a) REGULATIONS.—Before the expiration of the pe-  
 15 riod specified in subsection (b), the Secretary of Health  
 16 and Human Services shall promulgate regulations to carry  
 17 out the amendments to the Federal Food, Drug, and Cos-  
 18 metic Act that are made by sections 201 and 202.

19 (b) EFFECTIVE DATE.—The amendments to the Fed-  
 20 eral Food, Drug, and Cosmetic Act that are made by sec-  
 21 tions 201 and 202 take effect upon the expiration of the  
 22 one-year period beginning on the date of the enactment  
 23 of this Act, without regard to whether the regulations re-  
 24 quired in subsection (a) have been promulgated.

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